Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Second-line hormonal therapy for men with chemotherapy-naïve, castration-resistant prostate cancer: American Society of Clinical Oncology provisional clinical opinion.

Bibliographic Source(s)

Virgo KS, Basch E, Loblaw DA, Oliver TK, Rumble RB, Carducci MA, Nordquist L, Taplin ME, Winquist E, Singer EA. Second-line hormonal therapy for men with chemotherapy-naÃ¯ve, castration-resistant prostate cancer: American Society of Clinical Oncology provisional clinical opinion. J Clin Oncol. 2017 Jun 10;35(17):1952-64. [77 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
YES	Multidisciplinary Group

YES	Methodologist Involvement
▮▮▮▯▯	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▯	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▯▯▯	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▯▯	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▮▯▯	External Review
▮▮▮▮▮	Updating

Recommendations

Major Recommendations

This provisional clinical opinion (PCO) addresses the following main research question: Do second-line hormonal therapies play a role in the treatment of chemotherapy-naïve men with castration-resistant prostate cancer (CRPC)?

Research Question 1

Should a castrate state be maintained in patients who develop CRPC?

PCO 1

For men who develop CRPC despite castrate levels of testosterone:

> Patients should be maintained in a castrate state indefinitely. This PCO is based on indirect scientific evidence and current understandings of disease progression mechanisms in prostate cancer. A discussion with patients about the limited nature of available scientific evidence and the balance among potential harms, benefits, costs, and patient preferences is essential when planning treatment.
> A castrate state should be maintained through orchiectomy or pharmacologic castration (e.g., luteinizing hormone–releasing hormone [LHRH] agonists/antagonists, antiandrogens).

Research Question 2

In chemotherapy-naÄ±ve patients who develop CRPC but have no radiographic evidence of metastases (M0 CRPC), should second-line hormonal therapies be used? If so, what agents or specific sequence of agents should be offered?

PCO 2

For chemotherapy-naïve patients believed to be at low risk for metastases (low prostate-specific antigen [PSA] and slow PSA doubling time) (Pound et al., 1999; Scher et al., 2016), second-line hormonal therapies are not suggested.
For chemotherapy-naïve patients at high risk of developing metastases (rapid PSA doubling time or velocity), second-line hormonal therapies that lower PSA values or slow the rate of PSA rise may be offered (preferably in a clinical trial setting where available) after discussion with the patient about limited scientific evidence, potential harms, benefits, costs, and patient preferences.
Alternative treatment options include observation (with maintenance of a castrate state) or participation in a clinical trial.
Chemotherapy or immunotherapy is not suggested except in a clinical trial.
No evidence provides guidance about the optimal order of hormonal therapies after second-line hormonal therapy for high-risk chemotherapy-naÄ±ve patients with M0 CRPC. The panel was unable to come to consensus about sequencing.

Research Question 3

In chemotherapy-naïve patients who develop CRPC and have radiographic evidence of metastases but minimal symptoms (M1a/ M1s CRPC), should second-line hormonal therapies be used? If so, what agents are recommended?

PCO 3

After first-line hormonal treatment failure and a discussion with chemotherapy-naïve patients about potential harms, benefits, costs, and patient preferences:

Abiraterone acetate plus prednisone should be offered because they significantly improved radiographic progression-free survival (rPFS) and overall survival (OS) as well as secondary end points, including median time to opiate use, chemotherapy initiation, performance status deterioration, and PSA progression (v prednisone alone). The drugs are also well tolerated.
Enzalutamide should be offered because it significantly improves rPFS and OS. Secondary end points are also improved, including time to initiation of cytotoxic chemotherapy, risk of a first skeletal-related event, complete or partial soft tissue response, time to PSA progression, time to deterioration in quality of life, and decline in PSA of ≥50% from baseline (v placebo). The drug is also well tolerated.
Alternative treatment options include immunotherapy (sipuleucel-T) (Kantoff et al., 2010), chemotherapy (docetaxel and prednisone) (Basch et al., 2014), and radium-223.
If none of these therapies can be obtained or tolerated by the patient, other antiandrogens, prednisone, and ketoconazole/hydrocortisone may be offered because they provide modest clinical benefits in this population, but no survival benefits have been established.
Other alternative treatment options include enrollment in a clinical trial and observation.
No evidence provides guidance about the optimal order of hormonal therapies after second-line hormonal therapy for patients with M1 CRPC. The panel was unable to come to a consensus about sequencing.
Other second-line hormonal therapy options where results from phase III trials are pending are not suggested.
Palliative care should be offered to all chemotherapy-naÄ±ve men with M1 CRPC, particularly to those who exhibit symptoms or decreased quality of life (refer to the National Guideline Clearinghouse [NGC] summary of the ASCO guideline Integration of palliative care into standard oncology care: American Society of Clinical Oncology clinical practice guideline update).

Research Question 4

How often should patients with CRPC undergo PSA monitoring?

PCO 4

No evidence provides guidance about the optimal frequency of PSA monitoring before starting second-line hormonal therapy or after treatment has begun.

> For patients with no radiographic evidence of metastases and a slow PSA doubling time (Pound et al., 1999; Scher et al., 2016) or velocity, a PSA evaluation every 4 to 6 months is reasonable. If PSA levels rise, checking serum testosterone levels should be considered.
> For patients with a rapid PSA doubling time, velocity, or radiographic evidence of metastases, a PSA evaluation every 3 months is reasonable.

Research Question 5

What imaging modalities are appropriate for patients with CRPC?

PCO 5

> When imaging is considered for patients both before and while receiving treatment, a bone scan and either computed tomography or magnetic resonance imaging of the abdomen and pelvis are reasonable.
>
> Imaging with fluorine-18 (^{18}F)-labeled positron emission tomography (^{18}FPET) generally is not recommended because it is currently only approved in the United States for the diagnosis of recurrent prostate cancer among men with elevated PSA after treatment. The use of this technique is otherwise limited to patients who participate in clinical trials and prospective registries.

Research Question 6

How often should patients with CRPC undergo radiographic imaging or routine radiographic restaging?

PCO 6

> Radiographic imaging is not indicated for men with rising PSA unless treatment selection would be altered on the basis of radiographic findings or if symptoms potentially attributed to prostate cancer develop or worsen (e.g., bone pain).
> Routine radiographic restaging generally is not recommended, except among patients in whom PSA is not a reliable marker of disease.

Clinical Algorithm(s)

An algorithm titled "Algorithm for second-line hormonal castration-resistant prostate cancer (CRPC) treatment" is provided in the appendix of the original guideline document.

Scope

Disease/Condition(s)

Castration-resistant prostate cancer (CRPC)

Guideline Category

Management

Treatment

Clinical Specialty

Oncology

Radiation Oncology

Radiology

Urology

Intended Users

Advanced Practice Nurses

Patients

Physician Assistants

Physicians

Guideline Objective(s)

To address second-line hormonal therapy for chemotherapy-naïve men with castration-resistant prostate cancer (CRPC) who range from being asymptomatic with only biochemical evidence of CRPC to having documented metastases but minimal symptoms

Target Population

Chemotherapy-naïve men with castration-resistant prostate cancer (CRPC) maintained in a continuous or intermittent castrate state through orchiectomy or pharmacologic castration; the primary target are asymptomatic men but also includes those with minimal symptoms

Interventions and Practices Considered

1. Maintenance of a castrate state through orchiectomy or pharmacologic castration (e.g., luteinizing hormone–releasing hormone [LHRH] agonists/antagonists, antiandrogens)
2. Use of second-line hormonal therapies
    - Abiraterone acetate plus prednisone
    - Enzalutamide
    - Immunotherapy (sipuleucel-T)
    - Chemotherapy (docetaxel and prednisone)
    - Radium-223
    - Other antiandrogens
    - Prednisone
    - Ketoconazole/hydrocortisone
3. Palliative care
4. Frequency of prostate-specific antigen (PSA) monitoring
5. Radiographic imaging
    - Bone scan
    - Computed tomography of the abdomen and pelvis
    - Magnetic resonance imaging of the abdomen and pelvis
    - Imaging with fluorine-18 (18F)-labeled positron emission tomography (^{18}FPET) (not recommended routinely)

Major Outcomes Considered

- Overall survival (OS)
- Progression-free survival
- Prostate-specific antigen (PSA) response (defined as a decline in PSA >50%)
- Objective response
- Adverse events
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Systematic Literature Review

The American Society of Clinical Oncology (ASCO) provisional clinical opinions (PCOs) are based in part on systematic reviews of the literature. A protocol for each systematic review defines parameters for a targeted literature search. Additional parameters include relevant study designs, literature sources, types of reports, and pre-specified inclusion and exclusion criteria for literature identified. The protocol for this PCO was reviewed and approved by the ASCO Clinical Practice Guidelines Committee's Genitourinary Cancer Guideline Advisory Group (GAG).

PCO Development Process

This PCO was informed by a systematic review of the available evidence, consensus opinion, and clinical experience. Articles were selected for inclusion in the systematic review of the evidence on the basis of the following criteria:

> Chemotherapy-naive men with nonmetastatic or metastatic castration-resistant prostate cancer (CRPC) who were being considered for second-line hormonal therapy
> Measured effect of continued hormonal interventions in patients with CRPC for at least one primary measure of therapeutic efficacy, such as radiographic progression-free survival (rPFS), overall survival (OS), time to prostate specific antigen (PSA) progression or time to progression in general, and median duration of response
> A minimum of 25 patients per trial arm

Articles were excluded from the systematic review if they were (1) meeting abstracts not subsequently published in peer-reviewed journals; (2) editorials, commentaries, letters, news articles, case reports, or narrative reviews; and (3) published in a non-English language.

Literature Search Strategy

The search included the MEDLINE (PubMed: 1985 through June 2015), and Cochrane Library databases to May 31, 2014). Conference proceedings from the 2010–2015 ASCO Annual and Genitourinary meetings were also searched for randomized controlled trials reporting on outcomes of interest. Reference lists of seminal papers and recent review articles were scanned for additional citations. Literature search terms included castration-resistant prostate cancer, androgen-independent prostate cancer, and hormone

therapy. Further details on the search strategy and results are provided in the accompanying Data Supplement 1 (see the "Availability of Companion Documents" field).

A Quality of Reporting of Meta-analyses (QUOROM) Diagram illustrating the article selection process is available in Data Supplement 2.

Number of Source Documents

Six phase III randomized trials were identified in the systematic review of the evidence. Upon review of the available evidence, the Expert Panel concluded that the majority of the evidence was insufficient to inform evidence-based recommendations and that formal expert consensus would be needed to help inform clinical opinions.

See the Quality of Reporting of Meta-analyses (QUOROM) Diagram (Data Supplement 2) in the Data Supplement (see the "Availability of Companion Documents" field) for an outline of the study selection process.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Guide for Rating Quality of Evidence

Rating for Strength of Evidence	Definition
High	High confidence that the available evidence reflects the true magnitude and direction of the net effect (i.e., balance of benefits v harms) and that further research is very unlikely to change either the magnitude or direction of this net effect.
Intermediate	Moderate confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research is unlikely to alter the direction of the net effect; however, it might alter the magnitude of the net effect.
Low	Low confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research may change either the magnitude and/or direction of this net effect.
Insufficient	Evidence is insufficient to discern the true magnitude and direction of the net effect. Further research may better inform the topic. The use of the consensus opinion of experts is reasonable to inform outcomes related to the topic.

Guide for Rating of Potential for Bias

Rating of Potential for Bias	Definitions for Rating Potential for Risk of Bias in Randomized Controlled Trials
Low risk	No major features in the study that risk biased results, and none of the limitations are thought to decrease the validity of the conclusions. The study avoids problems such as failure to apply true randomization, selection of a population unrepresentative of the target patients, high dropout rates, and no intention-to-treat analysis; and key study features are described clearly (including the population, setting, interventions, comparison groups, measurement of outcomes, and reasons for dropouts).
Intermediate	The study is susceptible to some bias, but flaws are not sufficient to invalidate the results. Enough of the items introduce some uncertainty about the validity of the conclusions. The study does not meet all the criteria required for a rating of good quality, but no flaw is likely to cause major bias. The study may be missing

Definitions for Rating Potential for Risk of Bias in Randomized Controlled Trials	
Rating of Potential for Bias	
High risk	information, making it difficult to assess limitations and potential problems. There are significant flaws that imply biases of various types that may invalidate the results. Several of the items introduce serious uncertainty about the validity of the conclusions. The study has serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction

Search results were reviewed by the Practice Guidelines Specialist and papers deemed eligible for full text review were obtained and data were extracted. These data were also reviewed by the lead authors and audited by a second American Society of Clinical Oncology (ASCO) staff member. Disagreements were resolved through discussion and consultation with the lead authors if necessary. Evidence tables are provided in the original guideline document.

Study Quality Assessment

Study quality was formally assessed for the studies identified. For the ASCO quality assessment, design aspects related to the individual study quality were assessed by one reviewer and included factors such as blinding, allocation concealment, placebo control, intention to treat, funding sources, etc. The risk of bias is assessed as "low," "intermediate," or "high" for the identified evidence (see the "Rating Scheme for the Strength of the Evidence" field).

Quality Assessment of the Literature

The modest number of randomly assigned patients in the majority of the identified trials created obstacles with respect to determination of the true efficacy or generalizability of the findings. An additional challenge with the data identified by the systematic review was the lack of similar treatment arms; no two trials included the same comparisons. The largest trial included 1,717 participants. However, most of the remaining trials included fewer than 140 patients per comparison arm. The trial of abiraterone acetate in chemotherapy-naive patients reported significant progression-free survival (PFS) results, which led to the trial being stopped early. The enzalutamide trial in chemotherapy-naive patients also reported a PFS advantage and was stopped early. Patients were offered crossover in both studies.

Methods Used to Formulate the Recommendations

Expert Consensus

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Expert Panel Composition

The American Society of Clinical Oncology (ASCO) Clinical Practice Guidelines Committee (CPGC) convened an Expert Panel that comprised prostate cancer experts with specific knowledge in and clinical experience with CRPC, including specialists from medical oncology, urologic oncology, radiation oncology, and guideline methodology. Academic and community practitioners were represented as were patients.

Consensus Panel Composition

In addition to the Expert Panel, the ASCO CPGC also convened a Consensus Panel, with similar representation to the Expert Panel, tasked with rating agreement with the drafted provisional clinical opinions (PCOs) by using ASCO's formal consensus-based methodology. This approach is based on the modified Delphi consensus development methodology for providing clinical guidance when available data do not support more traditional and definitive evidence-based recommendations. Results of the consensus ratings can be found in Data Supplement 8 (see the "Availability of Companion Documents" field).

PCO Development Process

The Expert Panel, who met via teleconference and corresponded through email, was asked to contribute to the development of the PCO, provide critical review, interpret evidence, and finalize the PCO in consideration of the evidence. The Expert Panel was supplemented by additional experts recruited to rate their agreement with the drafted PCOs as part of the consensus process. The entire membership of experts is referred to as the Consensus Panel. The Expert Panel and ASCO staff prepared the draft PCOs for review and rating by the Consensus Panel.

Development of the PCO

The PCOs were crafted, in part, using the GuideLines Into DEcision Support (GLIDES) methodology and accompanying BRIDGE-Wiz software™. This method helps panels systematically develop clear, translatable, and implementable guidance using natural language, based on the evidence and assessment of its quality to increase usability for end users. The process incorporates distilling the actions involved, identifying who will carry them out, to whom, under what circumstances, and clarifying if and how end users can carry out the actions consistently. This process helps the panel focus the discussion, avoid using unnecessary and/or ambiguous language, and clearly state its intentions.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The guideline developers reviewed published cost analyses.

Refer to "Cost Implications" section for an analysis of economic impact.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Members of the Expert Panel are responsible for drafting the penultimate version of the provisional clinical opinion (PCO), which is then circulated for external review and submitted to the *Journal of Clinical Oncology* for editorial review and publication. All American Society of Clinical Oncology (ASCO) PCOs are reviewed and approved by the ASCO Clinical Practice Guideline Committee prior to publication. The Clinical Practice Guidelines Committee (CPGC) approved the guideline on February 7, 2017.

The PCO is approved by a unanimous vote of (1) the PCO Expert Panel members; (2) the CPGC leadership (Past-Chair, Chair, Chair-Elect, and ASCO Board Liaison) and selected content experts drawn from the CPGC membership and/or selected content experts appointed at the discretion of the CPGC Chair.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Basch E, Loblaw DA, Oliver TK, Carducci M, Chen RC, Frame JN, Garrels K, Hotte S, Kattan MW, Raghavan D, Saad F, Taplin ME, Walker-Dilks C, Williams J, Winquist E, Bennett CL, Wootton T, Rumble RB, Dusetzina SB, Virgo KS. Systemic therapy in men with metastatic castration-resistant prostate cancer: American Society of Clinical Oncology and Cancer Care Ontario clinical practice guideline. J Clin Oncol. 2014 Oct;32(30):3436-48. [65 references] PubMed

Kantoff PW, Higano CS, Shore ND, Berger ER, Small EJ, Penson DF, Redfern CH, Ferrari AC, Dreicer R, Sims RB, Xu Y, Frohlich MW, Schellhammer PF, IMPACT Study Investigators. Sipuleucel-T immunotherapy for castration-resistant prostate cancer. N Engl J Med. 2010;363(5):411-22. PubMed

Pound CR, Partin AW, Eisenberger MA, Chan DW, Pearson JD, Walsh PC. Natural history of progression after PSA elevation following radical prostatectomy. JAMA. 1999;281(17):1591-7.

Scher HI, Morris MJ, Stadler WM, Higano C, Basch E, Fizazi K, Antonarakis ES, Beer TM, Carducci MA, Chi KN, Corn PG, de Bono JS, Dreicer R, George DJ, Heath EI, Hussain M, Kelly WK, Liu G, Logothetis C, Nanus D, Stein MN, Rathkopf DE, Slovin SF, Ryan CJ, Sartor O, Small EJ, Smith MR, Sternberg CN, Taplin ME, Wilding G, Nelson PS, Schwartz LH, Halabi S, Kantoff PW, Armstrong AJ, Prostate Cancer Clinical Trials Working Group 3. Trial design and objectives for castration-resistant prostate cancer: updated recommendations from the Prostate Cancer Clinical Trials Working Group 3. J Clin Oncol. 2016 Apr;34(12):1402-18. PubMed

Type of Evidence Supporting the Recommendations

Six phase III randomized controlled trials and expert consensus opinion inform this provisional clinical opinion.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Goals of treatment in men with castration-resistant prostate cancer include chemotherapy deferral and palliation, that is, symptom relief with extension of life while maximizing quality of life for as long as possible or as a pre-emptive intervention against symptoms. Despite resistance to initial androgen deprivation therapy (first-line hormonal therapy), most men respond to second-line hormonal therapies.

Refer to the "Literature review and analysis" and "Clinical interpretation" sections of the original guideline document for a discussion of the potential benefits of each provisional clinical opinion.

Potential Harms

- Multiple adverse effects and harms were reported with androgen deprivation therapy (ADT), including hot flushes, fatigue, impotence, gynecomastia, loss of libido, osteoporosis, and a risk for metabolic syndrome.
- According to the manufacturer's warnings and precautions, abiraterone acetate should be used with caution in patients with a history of cardiovascular disease. Drug safety was not established in patients with a left-ventricular ejection fraction <50% or with New York Heart Association class II to

IV disease. Abiraterone acetate can cause hypertension, hypokalemia, and fluid retention. Low risks of adrenocortical insufficiency or hepatotoxicity also are associated with abiraterone acetate use. A low risk of seizure associated with enzalutamide use exists; however, among chemotherapy-naïve patients, the risk (0.1%) was similar between those who received enzalutamide and those who received placebo. Posterior reversible encephalopathy syndrome also has been associated with enzalutamide use, which required discontinuation of the drug.

Refer to the "Literature review and analysis" sections of the original guideline document for a discussion of the potential harms of each provisional clinical opinion.

Qualifying Statements

Qualifying Statements

- The clinical practice guidelines and other guidance published herein are provided by the American Society of Clinical Oncology, Inc (ASCO), to assist providers in clinical decision making. The information therein should not be relied upon as being complete or accurate, nor should it be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. With the rapid development of scientific knowledge, new evidence may emerge between the time information is developed and when it is published or read. The information is not continually updated and may not reflect the most recent evidence. The information addresses only the topics specifically identified therein and is not applicable to other interventions, diseases, or stages of diseases. This information does not mandate any particular course of medical care. Further, the information is not intended to substitute for the independent professional judgment of the treating provider, as the information does not account for individual variation among patients. Recommendations reflect high, moderate, or low confidence that the recommendation reflects the net effect of a given course of action. The use of words like "must," "must not" "should," and "should not" indicate that a course of action is recommended or not recommended for either most or many patients, but there is latitude for the treating physician to select other courses of action in individual cases. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. ASCO provides this information on an "as is" basis, and makes no warranty, express or implied, regarding the information. ASCO specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. ASCO assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information or for any errors or omissions.
- Opinions expressed in the guideline should not be interpreted as the official positions of any US or Canadian governmental agency, including the National Cancer Institute, National Institutes of Health, the Food and Drug Administration, or the US Department of Health and Human Services.
- Refer to the "Health Disparities" and "Multiple Chronic Conditions" sections in the Data Supplement and "Limitations of the Literature and Future Directions" section in the original guideline document, as well as the "Provisional Clinical Opinion Note" in the slide set for additional qualifying information (see the "Availability of Companion Documents" field).

Implementation of the Guideline

Description of Implementation Strategy

For information on the American Society for Clinical Oncology (ASCO) implementation strategy, please see the ASCO Web site .

Implementation Tools

Clinical Algorithm

Patient Resources

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

End of Life Care

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Virgo KS, Basch E, Loblaw DA, Oliver TK, Rumble RB, Carducci MA, Nordquist L, Taplin ME, Winquist E, Singer EA. Second-line hormonal therapy for men with chemotherapy-naÃ¯ve, castration-resistant prostate cancer: American Society of Clinical Oncology provisional clinical opinion. J Clin Oncol. 2017 Jun 10;35(17):1952-64. [77 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Jun 10

Guideline Developer(s)

American Society of Clinical Oncology - Medical Specialty Society

Source(s) of Funding

American Society of Clinical Oncology (ASCO)

Guideline Committee

American Society of Clinical Oncology (ASCO) Castration-Resistant Prostate Cancer Expert Panel

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Financial Disclosures/Conflicts of Interest

Provisional Clinical Opinion (PCO) and Conflicts of Interest

The Expert Panel was assembled in accordance with American Society of Clinical Oncology (ASCO)'s Conflict of Interest Policy Implementation for Clinical Practice Guidelines ("Policy," found at www.asco.org/rwc). All members of the panel completed ASCO's disclosure form, which requires disclosure of financial and other interests, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the guideline. Categories for disclosure include employment; leadership; stock or other ownership; honoraria; consulting or advisory role; speakers' bureau; research funding; patents, royalties, other intellectual property; expert testimony; travel, accommodations, expenses; and other relationships. In accordance with the Policy, the majority of the members of the panel did not disclose relationships constituting a conflict under the Policy.

Authors' Disclosures and Potential Conflicts of Interest

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to www.asco.org/rwc or ascopubs.org/jco/site/ifc.

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No relationship to disclose

Ethan Basch
No relationship to disclose

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Honoraria: Amgen, AstraZeneca, GlaxoSmithKline (I),Merck (I), Bristol-Myers Squibb (I), Novartis (I), Roche (I), Janssen Pharmaceuticals, Astellas Pharma, AbbVie, Bayer AG, Ferring Pharmaceuticals
Consulting or Advisory Role: GlaxoSmithKline (I), Merck (I), Bristol-Myers Squibb (I), Novartis (I), Roche (I), Amgen, Astellas Pharma, Janssen Pharmaceuticals, Atlas Global Healthcare, AbbVie, Ferring Pharmaceuticals, Bayer AG
Patents, Royalties, Other Intellectual Property: Prostate immobilization device (GU-Lok)
Travel, Accommodations, Expenses: Janssen Pharmaceuticals, Amgen, Astellas Pharma
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Consulting or Advisory Role: Medivation, Janssen Pharmaceuticals, Ortho-McNeil Pharmaceutical, Tokai Pharmaceuticals, Bayer AG, Guidepoint Global, Best Doctors, Gerson Lehrman Group, UpToDate, Clovis Oncology, Research to Practice, Dava Oncology, Grand Rounds
Research Funding: Janssen Pharmaceuticals, Ortho-McNeil Pharmaceutical, Medivation, Bayer AG, Tokai Pharmaceuticals (Inst)
Travel, Accommodations, Expenses: Medivation, Janssen Pharmaceuticals, Tokai Pharmaceuticals, Clovis Oncology

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Honoraria: Merck, Bayer AG
Research Funding: Exelixis (Inst), Roche (Inst), Genentech (Inst), AstraZeneca (Inst), MedImmune (Inst), Medivation (Inst)

Eric A. Singer
No relationship to disclose

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Journal of Clinical Oncology Web site.

Availability of Companion Documents

The following are available:

- Second-line hormonal therapy for men with chemotherapy-naive, castration-resistant prostate cancer (CRPC): American Society of Clinical Oncology provisional clinical opinion. Methodology supplement. Alexandria (VA): American Society of Clinical Oncology; 2017. 14 p. Available from the American Society of Clinical Oncology (ASCO) Web site.
- Second-line hormonal therapy for men with chemotherapy-naive, castration-resistant prostate cancer (CRPC): American Society of Clinical Oncology provisional clinical opinion. Data supplements 1-8. Alexandria (VA): American Society of Clinical Oncology; 2017. 13 p. Available from the ASCO Web site.
- Second-line hormonal therapy for men with chemotherapy-naive, castration-resistant prostate cancer: American Society of Clinical Oncology provisional clinical opinion. Slide set. Alexandria (VA): American Society of Clinical Oncology; 2017. 21 p. Available in PowerPoint and PDF from the ASCO Web site.
- Second-line hormonal therapy for men with chemotherapy-naive, castration-resistant prostate cancer: American Society of Clinical Oncology provisional clinical opinion. Summary of recommendations. Alexandria (VA): American Society of Clinical Oncology; 2017. 3 p. Available from the ASCO Web site.

Patient Resources

The following is available:

- Prostate cancer. Patient information. 2017. Available from the Cancer.Net Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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